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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/287,632	04/07/1999	PETER MICHAEL WATERHOUSE	021565-060	6526

21839 7590 02/08/2007
BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/287,632	Applicant(s) WATERHOUSE ET AL.	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 22, 26, 40, 42-44, 46, 50, 53, 54, 56, 58 and 63-108 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 12, 40, 43, 44, 46, 50, 70-84, 98, 99, 104 and 105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 26, 42, 53, 54, 56, 58, 63-69, 85-97, 100-103 and 106-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11-22-06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communications filed 11-22-06.

Claims 1-10, 12, 22, 26, 40, 42-44, 46, 50, 53, 54, 56, 58 and 63-108 are pending in the instant application. Claims 1-10, 12, 40, 43, 44, 46, 50, 70-84, 98, 99, 104, 105 have been withdrawn as non-election inventions, and claims 22, 26, 42, 53, 54, 56, 58, 63-69, 85-97, 100-103, 106-108 have been examined on their merits as set forth below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-22-06 has been entered.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
to 37 CFR 1.114.

Claims 22, 26, 42, 53, 54, 56, 58, 63-69, 85-97, 100-103, 106-108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to plants, eukaryotic cells, and chimeric DNA comprising an operable promoter, transcription termination and polyadenylation region, and further comprising a DNA region encoding a region capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base pairing between regions with a sense and an antisense nucleotide sequence, which sense nucleotide sequence includes at least 10 consecutive nucleotides having 100% sequence identity with at least 10 consecutive nucleotides of a nucleic acid of interest, and which antisense sequence includes at least 10 consecutive nucleotides having 100%

sequence identity with said at least 10 consecutive nucleotides of the sense sequence, and which chimeric DNA further comprises any intronic sequence.

The specification, claims and the art do not adequately describe the distinguishing features or attributes concisely shared by the members of the broad genus comprising DNA constructs whereby any intronic sequence is inserted anywhere in the chimeric DNA, and whereby the DNA construct provides for the function claimed, of generating a gene silencing construct that reduces phenotypic expression of any nucleic acid of interest in any plant and in any eukaryotic cell.

The specification teaches fully complementary pair constructs for reducing the phenotypic expression of a transgenic Gus gene (of approximately 1580 base pairs), and complementary pair constructs for reducing the phenotypic expression of the $\Delta 12$ desaturase target gene in *Arabidopsis* (of approximately 620 base pairs) which complementary pair constructs additionally comprise the pyruvate orthophosphate dikinase 2 intron 2 from *Flaveria trinervia* (SEQ ID NO. 7) in forward or reverse orientation. The scope of the claims, however, includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between members of this very broad genus are permitted.

The specification fails to teach or adequately describe a representative number of species in the genus such that the common attributes or characteristics concisely identifying members of the proposed genus are exemplified (e.g. the myriad of sequences encompassed by the genus intron, or intronic sequences is vast, and further

whereby any intronic sequence is inserted anywhere within the DNA construct and a DNA chimeric construct generates a gene silencing construct which reduces the phenotypic expression of any nucleic acid of interest in any eukaryotic cell). And because the genus claimed is so highly variant, the description provided is insufficient whereby a representative number of chimeric constructs provide for the functions claimed, of reducing the phenotypic expression of any nucleic acid of interest in any eukaryotic cell or plant. One of skill in the art would reasonably conclude that the disclosure, at the time of filing, fails to provide a representative number of species to describe the broad genus claimed. Thus, Applicant was not in possession of the claimed genus.

Response to Arguments and Amendments

Applicant's arguments filed 11-22-06 have been fully considered but they are not persuasive. Applicant argues that adequate written description has been provided for the broad genus comprising plants, eukaryotic cells, and chimeric DNA comprising an operable promoter, transcription termination and polyadenylation region, and further comprising a DNA region encoding a region capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base pairing between regions with a sense and an antisense nucleotide sequence, which sense nucleotide sequence includes at least 10 consecutive nucleotides having 100% sequence identity with at least 10 consecutive nucleotides of a nucleic acid of interest, and which antisense

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sequence includes at least 10 consecutive nucleotides having 100% sequence identity with said at least 10 consecutive nucleotides of the sense sequence, and which chimeric DNA further comprises any intronic sequence. Applicant argues that no particular deficiency in written description has been identified by the Office, and that the general structures provided in the instant disclosure, along with the combined knowledge in the art, provide adequate support for describing the genus of chimeric constructs claimed. Applicant also argues that sufficient detail of the structural elements encompassed by the genus claimed have been provided in the instant disclosure to permit suppression of expression of any gene of interest using the broadly claimed chimeric constructs. Applicant provides post-filing art spanning the years 2000-2005, and emphasizing the work of Smith et al (Nature Vol. 407, pages 319-320, 2000) to illustrate possession of the broadly claimed genus.

Contrary to Applicant's assertions, the particular deficiencies of the instant disclosure in providing adequate written description for the broad genus of chimeric constructs, eukaryotic cells and plants claimed have been addressed. The specification teaches fully complementary pair constructs for reducing the phenotypic expression of a transgenic Gus gene (of approximately 1580 base pairs), and complementary pair constructs for reducing the phenotypic expression of the $\Delta 12$ desaturase target gene in *Arabidopsis* (of approximately 620 base pairs) which complementary pair constructs additionally comprise the pyruvate orthophosphate dikinase 2

intron 2 from *Flaveria trinervia* (SEQ ID NO. 7) in forward or reverse orientation. The specification fails to teach or adequately describe a representative number of species in the genus such that the common attributes or characteristics concisely identifying members of the proposed genus are exemplified (e.g. the myriad of sequences encompassed by the genus intron, or intronic sequences is vast, and further whereby any intronic sequence is inserted anywhere within the DNA construct and a DNA chimeric construct generates a gene silencing construct which reduces the phenotypic expression of any nucleic acid of interest in any eukaryotic cell).

Applicant is correct that post-filing publications have described several gene silencing constructs comprising well known intronic sequences. But, contrary to Applicant's assertions, neither the art nor the instant disclosure, at the time of filing, provided adequate description for the features encompassed by the claimed invention. Smith et al teach gene silencing constructs comprising the previously characterized intron-2 of flaveria Pdk, or intron-1 of Arabidopsis Fad2, located between the sense and antisense arms of the gene silencing construct (see fig. 1 on p. 320).

This example, as well as the examples provided in the instant disclosure, however, do not provide adequate description for the broad genus claimed. What's more, Smith posed questions regarding the ability to enhance gene silencing by inserting intronic sequences within gene silencing constructs. The questions posed by Smith (see p. 320, third paragraph from

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the end) are illustrative of the state of the art at the time the invention was made.

How does the presence of this intron enhance silencing efficiency? The process of intron excision from the construct by the spliceosome might help to align the complementary arms of the hairpin in an environment favouring RNA hybridization, promoting the formation of a duplex. Alternatively, splicing may transiently increase the amount of hairpin RNA by facilitating, or retarding, the hairpin's passage from the nucleus, or by creating a smaller, less nuclease-sensitive loop.

Contrary to Applicant's assertions, Applicant was not in possession, at time of filing, of the broad genus of plants, eukaryotic cells or DNA chimeric constructs claimed. For the reasons set forth above, the rejection under 35 U.S.C. 112, first paragraph, for lacking adequate written description, is maintained.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

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DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
1-25-07

JANE ZARA, PH.D.
PRIMARY EXAMINER